



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

S.D. Augustine

) Group No.: 3739
#17
11/20

Serial No.: 09/771,791

) Examiner: Kenneth G. Schopfer

Filed: January 29, 2001

) Docket No. AUGA17000025

For: **SURGICAL BARRIER DEVICE INCORPORATING AN INFLATABLE THERMAL BLANKET WITH A SURGICAL DRAPE TO PROVIDE THERMAL CONTROL AND SURGICAL ACCESS**

CERTIFICATION UNDER 37 CFR § 1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on November 10, 2003, in an envelope addressed to Mail Stop AF, Box 1450, Commissioner for Patents, Alexandria VA 22313-1450

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BRIEF ON APPEAL

In response to the Final Action mailed June 3, 2003, and in view of the Notice of Appeal mailed on September 3, 2002, the applicant submits this Brief on Appeal. This paper is submitted in triplicate, by first class mail on November 10, 2003, which is within two months of the Appeal date, taking into account the weekend of November 8-9, 2003.

The Board is respectfully requested to note the change of correspondence address for this application.

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REAL PARTY IN INTEREST

The real party in interest is Arizant Healthcare Inc., by assignment from Augustine Medical, Inc. Both Arizant Healthcare Inc. and Augustine Medical, Inc. are wholly-owned subsidiaries of Arizant, Inc., a privately-held Minnesota corporation.

RELATED APPEALS

There are no related appeals.

STATUS OF THE CLAIMS

Claims 58-70, 75-88, and 93-95 remain in the application and are reproduced for the Board's convenience in Appendix I. All of these claims have been rejected in the Final Action mailed June 3, 2003.

The Final Action continues to list claim 1 as being in the application. However, this claim was cancelled in the Amendment of March 19, 2003, and is not considered by the applicant in this Brief.

STATUS OF AMENDMENTS

An Amendment and Request for Reconsideration submitted by first class mail on March 19, 2003 was received by the United States Patent Office on March 24, 2003 according to the Office's stamp on the applicants' return post card. All previous amendments have been entered.

SUMMARY OF THE INVENTION

The invention is a surgical barrier device that combines an inflatable thermal blanket to control the temperature of a patient's body with a surgical drape and to provide a sterile barrier between a surgical field of the patient and other fields while the patient undergoes surgery.

The surgical barrier device is best seen deployed in FIGS. 10-17; construction details of the device are illustrated in FIGS. 18-23. Referring to FIGS. 10, 11, 18, 19, and 23, the surgical barrier device includes an inflatable thermal device 320 and a surgical drape 321. The inflatable device 320 is formed from a flexible base sheet 342 secured to a flexible upper sheet 340 along a peripheral seam 344. An inlet cuff 328 is formed in the inflatable device to receive the nozzle of an air hose and admit warm pressurized air from the nozzle to inflate the device 320.

Apertures 352 are open through the base sheet in order to exhaust warm air onto a patient. See the description at page 15, line 1 through page 16, line 16. The base sheet may be made from a flexible fibrous material, and the apertures may be formed in the base sheet during manufacture of the surgical barrier device, or may be the interstices between the fibers of which the base sheet is formed. The bath of warm air maintains the patient's body temperature, mitigating or even preventing the occurrence of hypothermia that frequently accompanies surgery.

As described at page 16, line 17 through page 17, line 26, and as illustrated in FIGS. 10, 11, 19, 21, and 23, the surgical drape 321 is attached to, or formed integrally with the inflatable device 320. In this regard, the surgical drape 321 may be an extension of the upper sheet 340, the base sheet 342, or both, or may be a separate sheet attached to the inflatable device 320. As FIG. 10 illustrates, the surgical drape 321 is sized to completely cover a patient so that the surgical barrier device may be deployed with a frame structure 368 to keep the patient's breathing unobstructed. In order to provide access to a surgical site on the patient, the surgical barrier device is provided with a window, or cutout, (such as 364 in FIGS. 10 and 11). The surgical site is isolated from the warmed air exhausted through the inflatable device by an attachment device, such as tape, that secures the drape to the patient in the vicinity of the surgical site.

At least four specific configurations of the surgical barrier device are illustrated and described in the application. FIGS. 10 and 11 show a surgical barrier device in which the inflatable device is for covering the pelvic area and lower extremities of a patient. FIGS. 12 and 13 show a surgical barrier device in which the inflatable device is for covering the chest and upper extremities of a patient. FIGS. 14 and 15 show a surgical barrier device in which the inflatable device is for covering the torso and upper extremities of a patient. FIGS. 16 and 17

show a surgical barrier device for use in lithotomic surgery in which the inflatable device is for covering the torso, upper extremities, and lower extremities of a patient while affording access to a surgical site in the patient's groin.

The surgical barrier device was invented in response to problems encountered when prior art inflatable thermal blankets were used during surgery to combat hypothermia. See the background at page 2, line 6 through page 3, line 6. When used during surgery, the blankets delivered pressurized warmed air which flowed beneath the blankets without any restriction whatsoever, including over the surgical site. Further, the drapes that had been formed in the prior art blankets did not provide secure isolation of surgical sites because they were not sterile, and because they were not sized for full body coverage. The surgical barrier device was invented to solve these problems.

ISSUES

The issues are:

1. whether claims 58, 59, 61, 63, 69, and 70 are anticipated by Augustine et al (USPN 5620482) and are therefore unpatentable under 35 U.S.C. §102(e);
2. whether claims 60, 62, 64-67, 75-85, 87, 88, and 93-95 are obvious in view of Augustine et al (USPN 5620482) and Irani (USPN 5405370) and therefore unpatentable under 35 U.S.C. §103.;
3. whether claim 68 is obvious in view of Augustine et al (USPN 5620482) and Collins (USPN 3750664) and therefore unpatentable under 35 U.S.C. §103.; and
4. whether claim 86 is obvious in view of Augustine et al (USPN 5620482) over Irani (USPN 5405370) and Collins (USPN 3750664) and therefore unpatentable under 35 U.S.C. §103.

GROUPING OF CLAIMS

Claims 58, 59, 61, 63, 69, and 70 stand or fall together.

Claims 60, 62, 64, 75-79, 80-82, 87, 88, and 93-95 stand or fall together.

Claims 65-67 and 83-85 stand or fall together.

Claims 68 and 86 stand or fall together.

ARGUMENT

Anticipation Rejection

Claims 58, 59, 61, 63, 69, and 70 are rejected for anticipation by Augustine et al. That rejection is in error and should be withdrawn for the following reasons.

Rejection of a claim for anticipation by a reference requires that the reference contain in its four corners all elements or steps of the rejected claim and all limitations thereof expressly or inherently.

Surgical Drape One issue in this anticipation rejection applies also to the obviousness rejection discussed later. That is, the meaning of the term “surgical drape.” All claims of this application are limited in one way or another by this term, and its meaning has been the subject of consideration and analysis in this application. Since the applicant has not defined this term in the specification, it must be given its plain meaning, that is, the meaning given to the term by those of ordinary skill in the art. See MPEP 2111.01. The plain meaning of the term “surgical drape” has been established by the applicant in the form of a reference submitted in the Amendment mailed on November 22, 2003. A copy of that reference is attached hereto as Appendix II.

The reference (Mahidal University SPECTRUM entitled “Ramathiboti Hospital Develops Simplified Surgical Drapes for Performing Caesarian Sections on HIV-Infected Mothers”) establishes that the term “surgical drape” has a known meaning in the art. In this regard, according to the first sentence of the second full paragraph of the reference, a “*surgical drape*” or sterile covering, is used to form an aseptic field to prevent transportation of microorganisms.” As the applicant has consistently and continuously pointed out, a surgical drape or any drape having these functions is missing from Augustine et al and is not found in any other reference in the file of this application.

Claims 58, 59, 61, 63, 69, and 70

Claim 58, which is representative of this group of claims, sets forth a combination for use in surgery on a person that includes a base sheet, a material sheet attached to the base sheet to form an inflatable portion, apertures in the base sheet and “a surgical drape attached to, or formed integrally with, the inflatable portion.” Augustine et al. does not describe or illustrate a “surgical drape” in any thermal blanket embodiment. The reference describes a “foot drape 90” for a full body blanket shown in FIGS. 1 and 2, and a “foot drape 190” for a lower body blanket shown in FIGS. 6 and 7. Each foot drape “traps and retains heat around the patient’s feet to warm the feet.” (See Augustine et al. at column 7, lines 54-57 and column 8, lines 46-48). The reference also describes a plastic head drape adhesively attached to an upper body blanket

shown in FIGS. 10 and 11 and draped over a patient's head "to direct warmed air to the head area." (See Augustine et al. at column 10 lines 3-5). None of these drapes is described as a "surgical drape"; none of these drapes is described in connection with surgery, sterility, or provision of access to a surgical site. In short, the inflatable thermal blankets described by Augustine et al. omit a "surgical drape." Consequently, the applicant has timely requested the introduction of extrinsic evidence establishing that the missing surgical drape is necessarily in the inflatable thermal blanket described and would be recognized as being so by the skilled artisan. *In re Robertson*, 49 USPQ2d 1949 (CAFC, 1999).

Examiner's Remarks in the Final Rejection

In response to the request for extrinsic evidence, there is only the statement in the Final Action that "the drape of the present invention and the drape of Augustine are formed of the same materials ... and *can* perform the same functions ... both drapes *can* be used as a sterile covering ...". (italics added for emphasis). These are conclusions, unsupported by a reference or by an affidavit or even by reasoning. They constitute the Examiner's opinion about possible uses of the drapes of Augustine et al. They do not constitute extrinsic evidence required to support inherency. How is a surgical drape "necessarily" in the description of a foot drape? A foot drape traps air, while a surgical drape affords a sterile surgical environment. A foot drape is not deployed or positioned for defining and protecting a surgical environment, but a "surgical drape" is. Patient warming and comfort are the objectives achieved by a foot drape according to Augustine et al., support of surgery is not. See *In re Robertson*.

In the Final Rejection, the Examiner further states that the reference in Appendix II is "extrinsic evidence" that "the foot drape of Augustine et al. can clearly be classified as a surgical drape." The Examiner contends that the reference "states that a surgical drape is a 'sterile covering ...used to form an antiseptic field to prevent the transportation of microorganisms.' The foot drape of Augustine et al. is a sterile covering that will prevent transportation of microorganisms." The applicant agrees with the first part of the statement, which merely restates the plain meaning of the term "surgical drape". However, the second part of the statement is conclusory, and simply forces the result that "a foot drape is a sterile covering that will prevent the transport of microorganisms." No extrinsic evidence in the file establishes that a surgical drape is necessarily in the thermal blankets described by Augustine and that it would be so recognized by persons of ordinary skill. See *In re Robertson*.

Accordingly, the rejection of claims 58, 59, 61, 63, 69, and 70 should be withdrawn.

Obviousness Rejections

Claims 60, 62, 64-67, 75-85, 87, 88 and 93-95 were rejected under 35 U.S.C. 103(a) as being unpatentable over Augustine et al. (USPN 5620482) in view of Irani (USPN 5405370). Claim 68 has been rejected over Augustine et al in view of Collins. And, claim 86 has been rejected over Augustine in view of Irani and Collins. These rejections are traversed as follows.

Claims 60, 62, 64, 75-79, 80-82, 87, 88, and 93-95

The rejected claims recite a combination including “inflatable device” that is “sized and configured to cover one or more partial portions of a body”, “a surgical drape attached to, or formed integrally with, the inflatable device, and extending beyond the periphery, the surgical drape being sized and configured to cover additional portions of the body”, and “an opening formed in the surgical drape for accessing a surgical site on the body.” (Precisely, claims 60, 62, and 64 are somewhat more broadly directed, but are treated commonly with the other claims of this group). The Final Rejection proposes that “Augustine et al. teach the limitations of the claims except an opening and the inflatable portion being configured to cover the upper and lower extremities. Irani discloses a similar blanket where the inflatable portion is configured to cover the upper and lower extremities and teaches that it is old and well known in the art to provide an opening in the blanket to provide access through the blanket to perform a surgical procedure.” This is incorrect for the following reasons.

Graham Factual Inquiries

An invention is unpatentable only if the differences between it and the prior art would have been obvious at the time of the invention.

At the time the invention recited in the rejected claims was made, Augustine et al. taught foot drapes and head drapes to trap warmed air, and Irani taught an inflatable thermal blanket made of a material that could be sterilized so as to eliminate the need for “a surgical drape or blanket”. The problem with either, or both, of these references was the inability to secure a surgical site with a surgical drape when use of an inflatable device accompanied surgery. The rejected claims solve this problem in a way that was unforeseeable to the skilled artisan at the time the invention was made. The only way that the skilled artisan can appreciate the solution proposed by the applicant is with reference to the applicant’s disclosure. But this constitutes a retrospective view from the time the invention was made; therefore, the nexus between Augustine et al. and Irani is the result of impermissible hindsight. See *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir., 1999) and MPEP 2141.01.III.

Furthermore, Augustine et al. is directed to the problem of maintaining a uniform temperature by retaining and trapping heat around a patient. (See Augustine et al. at column 3, lines 9-15). Irani's invention is directed to elimination of "an overlaying surgical drape or blanket." This is accomplished by selection of materials that permit the entirety of Irani's blanket to be sterilized. (See Irani at column 2, lines 1-5 and at column 7, lines 25-30). Irani therefore teaches away from solution of the problem solved with the applicant's invention: the combination of an inflatable device with a surgical drape. See MPEP 2142.02.

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Prima facie Obviousness

Prima facie, rejection of a claim for obviousness over a combination of references requires some suggestion or motivation to combine the references, a reasonable expectation of success, and the inclusion of all elements and limitations of the rejected claim in the combination or by suggestion. See MPEP 2142, et seq.

As set forth above, the invention of the rejected claims is a combination of "an inflatable device" and "a surgical drape." The term "surgical drape" has a plain meaning in the art that includes construction, form, and function. See the definition in Appendix II. Augustine et al. illustrate and describe foot and head drape configurations that are formed and function to trap heat, not to define a surgical site and maintain sterility thereof. No "surgical drape" is described, illustrated, or suggested in Augustine. Irani teaches away from use of a surgical drape. Therefore, there is no suggestion to combine Augustine et al. with Irani.

No reasonable expectation of success has yet been established in examination.

Finally, neither Augustine et al. nor Irani includes a surgical drape. As pointed out above, Augustine et al. teaches foot and head drapes that trap warmed air; but, these are not described as surgical drapes; and, no description of using the drapes to secure a surgical site is given. Indeed, the only references to "care sites" in Augustine et al. are in connection with elements 122 and 222, which are described as non-inflated recesses of the thermal blankets, not as drapes, surgical or otherwise. See Augustine et al. at column 8, lines 37-40. Furthermore, neither Augustine et al. nor Irani teach or suggest a "surgical drape being sized and configured to cover additional portions of the body", or "an opening formed in the surgical drape for accessing a surgical site on the body." Augustine et al. teach inflatable thermal blankets that are sized and configured to cover "selected areas of the patient". (See Augustine et al., Abstract) and drapes to warm the patient's feet and head. But Augustine et al. are silent with respect to "sizing and configuring" a surgical drape "to cover additional portions of the body." As conceded in the Final Action, Augustine et al. includes no openings in the foot drapes. Irani, however, only teaches an aperture 272 in an inflatable blanket 210, not in any drape. According to Irani, the

blanket 210 "includes an aperture 272 defined for example in a central portion of the blanket." (See Irani at column 7, lines 14-24). Neither reference teaches or suggests "an opening formed in the surgical drape for accessing a surgical site on the body."

Examiner's Remarks in the Final Rejection

In the Final Rejection it is contended that "Irani teaches as a blanket that serves as a surgical drape and has a surgical access opening." This statement is true, but only for what it teaches. What Irani teaches is use of an inflatable thermal blanket "as a surgical draping", not a surgical barrier device comprehending "an inflatable thermal blanket" in combination with "a surgical drape". Irani's intention in using a thermal blanket as surgical draping is to eliminate "the need to provide a separate warming blanket and draping material for a surgical operation". In contrast, the rejected claims provide a warming blanket (inflatable device) and draping material (surgical drape) for a surgical operation and an aperture in the surgical drape (not in the inflatable blanket).

not taught

Accordingly, the rejection of claims 60, 62, 64, 75-79, 80-82, 87, 88, and 93-95 should be withdrawn.

Claims 65-67 and 83-85

Claims 65-67 and 83-85 are directed to the lithotomic surgical barrier device of FIGS. 16 and 17. Claims 65-67 recite a surgical barrier device including an inflatable portion in combination with a surgical drape attached to or formed integrally with the inflatable portion in which "the surgical drape has a rectangular head end portion and a pair of foot end portions separated to define an opening". Claims 83-85 recite a surgical barrier device including an inflatable portion, a surgical drape attached to or formed integrally with the inflatable portion, and an opening formed in the surgical drape in which "the surgical drape has a generally rectangular head end portion and a pair of foot end portions separated by the opening". Augustine et al. describes and illustrates no lithotomic thermal blanket. Irani does not show a lithotomic thermal blanket having a surgical drape with an aperture defined by separate end portions of the drape, or a pair of foot end portions separated by the opening.

Accordingly, the rejection of claims 65-67 and 83-85 should be withdrawn.

Claims 68 and 86

Claims 68 and 86 have been rejected for obviousness over Augustine et al. in view of Collins and Augustine et al. in view of Irani and Collins. These two claims add to the respective claims from which they depend "a frame for supporting" the surgical drape or an end of the surgical drape. As already established, neither Augustine et al. nor Irani teach or suggest a

surgical barrier device combining an inflatable device with "a surgical drape". Collins does not rectify this omission.

Accordingly, the rejection of claims 68 and 86 should be withdrawn.

SUMMARY

For the reasons given above and for other good reasons of record in the file of this application, all of the claims remaining in this application are patentable distinct from the references of record, alone or in combination. The Board is therefore respectfully requested to reverse the rejections for anticipation and obviousness and direct that this application be allowed.

Respectfully submitted


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APPENDIX I

58. (Previously Added) A combination for use during surgery on a person, comprising:

a flexible base sheet;

a material sheet attached to a first surface of the base sheet by a plurality of seals to form an inflatable portion with a periphery, the inflatable portion having a periphery;

a plurality of apertures through the base sheet within the periphery; and

a surgical drape attached to, or formed integrally with, the inflatable portion.

59. (Previously added) A combination in accordance with claim 58, wherein the inflatable portion is for covering the pelvic region and lower extremities of the person, and the surgical drape is rectangular in shape.

60. (Previously Added) A combination in accordance with claim 59, wherein the inflatable portion has a recess at an end thereof, and the surgical drape includes an opening adjacent the recess.

61. (Previously added) A combination in accordance with claim 58, wherein the inflatable portion is configured to cover the chest and upper extremities of the person, and the surgical drape is rectangular in shape.

62. (Previously Added) A combination in accordance with claim 61, wherein the inflatable portion has a recess at a first end thereof and a recess at a second end thereof, and the surgical drape includes an opening adjacent the second end recess.

63. (Previously added) A combination in accordance with claim 58, wherein the inflatable portion is configured to cover the torso and upper extremities of the person, and the surgical drape is rectangular in shape.

64. (Previously added) A combination in accordance with claim 63, wherein the inflatable portion has a recess at a first end thereof and a recess at a second end thereof, and the surgical drape includes an opening adjacent the second end recess.

65. (Previously added) A combination in accordance with claim 58, wherein the inflatable portion is configured to cover the torso, the upper extremities and the lower extremities of the person, and the surgical drape has a rectangular head end portion and a pair of foot end portions separated to define an opening.

66. (Previously added) A combination in accordance with claim 65, wherein the inflatable portion has a recess at an end thereof, and the opening is adjacent to the recess.

67. (Previously added) A combination in accordance with claim 66, wherein the opening includes a longitudinal V-shaped notch and a transverse slit intersecting the head end of the notch.

68. (Previously added) A combination in accordance with claim 58, further including a frame for supporting the surgical drape.

69. (Previously added) A combination in accordance with claim 58, wherein the surgical drape is formed by an extension of the base sheet.

70. (Previously added) A combination in accordance with claim 58, wherein the surgical drape is formed by an extension of the material sheet.

Claims 71-74 (withdrawn)

75. (Previously added) A surgical barrier device, comprising;
an inflatable device that includes:
a flexible base sheet with two ends, two edges, and an undersurface;
the ends, and respective edges of the base sheet forming a periphery;
the base sheet including a layer of fibrous material on which the undersurface is disposed;
a material sheet attached to the base sheet by a seal near the periphery;
an inflating inlet for admitting a thermally controlled inflating medium into the inflatable device; and
the base sheet adapted for exhausting the thermally controlled inflating medium from the inflatable device through the undersurface;
the inflatable device being sized and configured to cover one or more partial portions of a body; and
a surgical drape attached to, or formed integrally with, the inflatable device, and extending beyond the periphery, the surgical drape being sized and configured to cover additional portions of the body; and
an opening formed in the surgical drape for accessing a surgical site on the body.

76. (Previously added) A surgical barrier device in accordance with claim 75, further including a plurality of seals between the material sheet and the base sheet within the periphery.

77. (Previously added) A surgical barrier device in accordance with claim 75 wherein the inflatable device is configured to cover the pelvic region and lower extremities of the body, and the surgical drape is generally rectangular in shape.

78. (Previously amended) A surgical barrier device in accordance with claim 77, wherein the inflatable device has a recess at an end thereof, and the opening is adjacent to the recess.

79. (Previously added) A surgical barrier device in accordance with claim 75, wherein the inflatable device is configured to cover the chest and upper extremities of the body, and the surgical drape is generally rectangular in shape.

80. (Previously added) A surgical barrier device in accordance with claim 75, wherein the inflatable device has a recess at a first end thereof and a recess at a second end thereof, and the opening is adjacent to the second end recess.

81. (Previously added) A surgical barrier device in accordance with claim 75, wherein the inflatable device is configured to cover the torso and upper extremities of the body, and the surgical drape is generally rectangular in shape.

82. (Previously added) A surgical barrier device in accordance with claim 81, wherein the inflatable device has a recess at a first end thereof and a recess at a second end thereof, and the opening is adjacent to the second end recess.

83. (Previously added) A surgical barrier device in accordance with claim 75, wherein the inflatable device is configured to cover the torso, the upper extremities and the lower extremities of the body, and the surgical drape has a generally rectangular head end portion and a pair of foot end portions separated by the opening.

84. (Previously added) A surgical barrier device in accordance with claim 83, wherein the inflatable device has a recess at an end thereof, and the opening is adjacent to the recess.

85. (Previously added) A surgical barrier device in accordance with claim 84, wherein the opening includes a longitudinal V-shaped notch and a transverse slit intersecting the head end of the notch.

86. (Previously added) A surgical barrier device in accordance with claim 75, further including a frame for supporting an end of the surgical drape.

87. (Previously added) A surgical barrier device in accordance with claim 75, wherein the surgical drape is formed by an extension of the base sheet.

88. (Previously added) A surgical barrier device in accordance with claim 75, wherein the surgical drape is formed by an extension of the material sheet.

Claims 89-92 (withdrawn)

93. (Previously added) A surgical barrier device in accordance with claim 75, wherein the plurality of apertures open through the surface in the inflatable device.

94. (Previously added) A surgical barrier device in accordance with claim 93 wherein the apertures include spaces between the fibers of the fibrous material.

95. (Previously added) A surgical barrier device in accordance with claim 93, wherein the apertures include multiple discrete holes in the base sheet.

APPENDIX II



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- Mahidol University Hosts the 10th Anniversary Prince Mahidol Awards Congress: Medicine and Public Health in the Postgenomic Era
- Official Launch of Thailand - Australia Social Protection Facility
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- Ramathibodi Hospital Develops Simplified Surgical Drapes for Performing Caesarean Sections on HIV-Infected Mothers
- MU Chairs 'Domestic and International Networking Forum'
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- MUIC Holds Business Management Training Course
- MU Debate Club Hosts International Tournament
- 29th SEAMIC Workshop on Health Documentation and Publication
- French and American Academics Deliver Special Lectures at MU
- New Faculty Appointments
- MU attends Education Exhibition in China
- College of Religious Studies Holds Peace Conference
- College of Music Recital: Mozart to Manhattan

Ramathibodi Hospital Develops Simplified Surgical Drapes for Performing Caesarean Sections on HIV-Infected Mothers

Surgeons and assistants are at risk of being infected while performing surgical procedures on HIV-positive patients, due to exposure to bodily fluids which can carry the virus. This is very true in the case of performing Caesarean sections (C-sections) -- delivery of a baby by cutting through the abdominal and uterine walls -- which involves exposure to both maternal blood and amniotic fluid. Equally important, it is also necessary to protect the newborn from possible infection.

Normally, a '**surgical drape**', or sterile covering, is used to form an aseptic field to prevent transportation of microorganisms. In the past, when few infectious diseases that could occur during pregnancy were known, reusable abdominal drapes and gowns were routinely used. However, the laundering of these possibly-contaminated materials is problematic, and eventually reduces their barrier qualities. Synthetic disposable drapes and gowns prove more effective in today's environment.

A problem, however, is that imported disposable drapes are more expensive, an important factor in developing countries when resources are limited. Furthermore, in the past no special vulvar drape existed for the prevention of surgical soiling during the operation. Doctors from MU's Ramathibodi Hospital have recently alleviated these problems by developing simplified disposable abdominal and vulvar drapes. The team responsible -- consisting of Dr. Winit Phuapradit, Professor and Chairman, and Dr. Panyu Panburana, Asst. Prof., both of the Dept. of Obstetrics and Gynaecology, along with Assoc. Prof. Weena Bullungpoti, Dept. of Nursing -- recently wrote of their invention in an article published in the International Journal of Gynaecology & Obstetrics.

Their efforts stem from encountering these obstacles while undertaking the '**Ramathibodi Elective Delivery Project**', implemented in October 1998 in response to the well-established fact that scheduled or elective C-section reduces the likelihood of accidental HIV-transmission, compared to vaginal delivery or unscheduled C-section. Elective C-section, performed before the onset of labor and consequent rupture of membranes, prevents transplacental maternal-fetal microtransfusion of blood and HIV during uterine contractions. Moreover, the infant is not exposed to infected cervicovaginal secretions and blood. C-section is thus widely recommended for HIV-infected mothers.

The Ramathibodi team made the simplified disposable abdominal

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drape from an ordinary polyethylene plastic bag, a transparent polyurethane acrylate glued sticker with paper backing, and two pieces of water-repellent, non-woven cloth. During the surgery, a square aperture is made in the center of one surface of the plastic bag, with the edge of the aperture elevated by flexible plastic bars. The sticker is mounted on the bag's other surface, adhering to the patient's abdomen after removal of the paper backing. The water-repellent cloths are attached to the upper and lower ends of the bag and all edges are sealed to prevent fluid leakage, forming a large rectangular '**collection pouch**' that covers the operative area to collect potentially contaminated fluids and thus prevent surgical soiling. The surgeon makes the incision through the plastic drape and the fetus is eventually delivered within the pouch.

The vulvar drape is made of an ordinary polyethylene plastic bag with its anterior surface cut off in a V-shape and two ovoid-shaped apertures made along the borders of the V-shaped edges. The upper plastic edges of these two apertures are cut in the middle, making the aperture size adjustable for strapping around the patient's upper thighs. A fluid back-flow-preventing mattress is placed along the posterior surface of the upper border of the bag. Contaminated fluids and blood from the vaginal canal are then collected within the pouch of this vulvar drape.

Senior obstetric staff at Ramathibodi Hospital employed these techniques in performing elective C-sections on 17 HIV-infected patients from March to September 1999. A study revealed that the procedures were well-tolerated by all patients, and that both drapes effectively prevented surgical soiling.

Both drapes are assembled and sterilized by ethylene oxide gas, available at the hospital, at a cost of only US\$ 5. These hospital-made simplified disposable drapes thus provide efficient collection and disposal of amniotic fluid and blood via abdominal incision and vaginal canal, thereby reducing the risk to the surgeons. This technique offers a safe and inexpensive draping method for elective C-section in cases of maternal HIV-infection. Moreover, it facilitates the role of elective C-section in cost-benefit terms for the reduction of perinatal HIV-transmission, especially in developing countries.

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